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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY
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09/240,675 02/02/99 BENOIT

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EXAMINER

DEVI, S

ART UNIT

PAPER NUMBER

1645

10

DATE MAILED:

09/08/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/240,675

Applicant(s)

Benoit et al.

Examiner

S. Devi, Ph.D.

Group Art Unit  
1645



☒ Responsive to communication(s) filed on 03/02/2000.

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1:136(a).

## Disposition of Claims

☒ Claim(s) 23-26 ~~is~~/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 24 and 26 ~~is~~/are rejected.

☒ Claim(s) 23 and 25 ~~is~~/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9.

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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### **DETAILED ACTION**

#### **Applicants' Amendment**

- 1) Acknowledgment is made of Applicants' amendment filed 03/02/00 (paper no. 9) in response to the Office Action mailed 09/03/99 (paper no. 7). With these, Applicants have amended the specification.

#### **Status of Claims**

- 2) Claims 27 and 28 have been canceled.  
Claims 23, 24 and 25 have been amended.  
Claims 23-26 are under examination.

#### **Information Disclosure Statements**

- 3) Acknowledgment is made of Applicants' Information Disclosure Statements filed 08/02/99 (paper no. 8) and 03/02/2000 (paper no. 9). The information referred to therein has been obtained from the parent case and considered. A signed copy is attached to this Office Action (paper no. 10).

#### **Applicants' Declaration under 37 C.F.R. § 1.132**

- 4) Acknowledgment is made of Applicant's Declaration filed 03/02/2000 (paper no. 9) under 37 C.F.R § 1.132.

#### **Objection Withdrawn**

- 5) The objection to the specification made in paragraph 6 of the Office Action mailed 09/03/99 (paper no. 7) is withdrawn in light of Applicants' amendment to the first paragraph of the specification.
- 6) The objection of claims 23-26 made in paragraph 8 of the Office Action mailed 09/03/99 (paper no. 7) is withdrawn in light of Applicants' amendments to the claims.

#### **Objection Maintained**

- 7) The objection to the drawings made in paragraph 7 of the Office Action mailed 09/03/99 (paper no. 7) is maintained for reasons set forth therein. Applicants state that they would respond to this objection upon allowance.

**Rejections Withdrawn**

- 8) The rejection of claims 23-25 made in paragraph 9 of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 101 as being directed to a non-statutory subject matter, is withdrawn in light of Applicants' amendments to the claims.
- 9) The rejection of claims 23-26 made in paragraph 10 of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the deposit issue, is withdrawn in light of Applicants' submission of Declaration of the availability of the hybridoma.
- 10) The rejection of claim 23 made in paragraph 11 of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' arguments.
- 11) The rejection of claims 24 and 25 made in paragraph 12 of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, first paragraph, as being non-enabled with regard to the scope, is withdrawn in light of Applicants' arguments and the Tovey Declaration.
- 12) The rejection of claims 23-26 made in paragraph 13 of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, first paragraph, as being non-enabled, is withdrawn.
- 13) The rejection of claims 23-26 made in paragraph 15(a) of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn.

**Rejection(s) Maintained**

- 14) The rejection of claim 26 made in paragraph 14 of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, first paragraph, as being non-enabled, is maintained for reasons set forth therein.

Applicants argue that peptides and polypeptides such as those claimed in the present application comprise a particular epitope or epitopes that is/are recognized by the antibody, and that "other parts of the molecule can be substituted without changing the binding affinity of the peptides or polypeptides with the antibody". Applicants contend that enough of specific guidance is provided in the specification to produce the desired mutant and to test its binding to the

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monoclonal antibody, 64G12 (see page 6 of Applicants' response filed 03/02/2000).

The Applicants' argument has been fully considered, but is not persuasive. Contrary to the Applicants' assertion, the art indicates that substitution of a amino acid(s) in parts of a protein or polypeptide molecule outside of the epitope can affect the binding between the antibody and the modified protein or polypeptide. For instance, with reference to VR1 and VR2 epitopes of Class 1 outer membrane protein of *Neisseria meningitidis*, McGuinnes *et al.* (*Mol. Microbiol.* 7: 505-514, Feb 1993) teach that "[a] single amino acid change within an epitope, or an amino acid deletion **outside** an epitope, were both associated with loss of subtype specificity resulting from a change in the predicted conformation at the apex of the loop structure" (see abstract) (Emphasis added). Similarly, McGuinnes *et al.* (*Lancet* 337: 514-517, March 1991) teach that a point mutation generating a single amino acid change in a P1.16-specific epitope in the VR2 region of the *porA* gene of a strain of *Neisseria meningitidis* of subtype P1.7,16 results in "striking changes in the structural and immunological properties of the class 1 protein" of this isolate (see abstract and page 514). The art, thus, reflects unpredictability in the functions of a protein or polypeptide that has an amino acid substitution within or outside an epitope. Therefore, in the instant case, undue experimentation would have been required by one of ordinary skill in the art to reproducibly practice the invention as claimed, due to the art-recognized unpredictability associated with the specific binding ability of a protein or polypeptide, the lack of specific guidance, the lack of evidence in the specification and the quantity of experimentation necessary. The rejection stands.

15) The rejection to claim 26 made in paragraph 15(b) of the Office Action mailed 09/03/99 (paper no. 7) under 35 U.S.C § 112, second paragraph, as being indefinite, is maintained for reasons set forth therein. This rejection has not been addressed by the Applicants.

#### **New Rejection(s)**

16) Applicants are asked to note the new rejections made in this Office Action. The Applicants' amendments necessitated the new ground(s) of rejection presented in this Office Action.

#### **Rejection(s) - 35 U.S.C. § 102**

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17) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18) Claim 24 is rejected under 35 U.S.C § 102(b) as being anticipated by Orten *et al.* (*Biochemistry*, Eighth Edition, The C.V. Mosby Company, Saint Louis, pp. 57-90, 1970).

The isolated peptide or polypeptide of claim 24 encompasses “a portion” of the amino acid sequence from position 27 to position 229 of SEQ ID NO. 1 or SEQ ID NO. 2. A peptide consisting of one or two amino acids falling in the region between position 27 to position 229 of SEQ ID NO. 1 or SEQ ID NO. 2 qualifies as “a portion”.

Orten *et al.* teach individual amino acids that form a “portion” of the recited amino acid sequences (see pages 59-61).

Claim 24 is anticipated by Orten *et al.*

19) Claim 24 is rejected under 35 U.S.C § 102(a) as being anticipated by Racaniello *et al.* (WO9203538).

A sequence search performed at the Office shows that, patent WO9203538 discloses a “portion” of a polypeptide with an amino acid sequence from position 27 to position 229 of the claimed SEQ ID NO. 2. See the attached search report.

Claim 24 is anticipated by Racaniello *et al.*

#### Objection(s)

20) Claims 23 and 25 are objected to for not drafting the last part of the claims in such a way that “a portion thereof” is ~~not~~ linked with the function of specific binding with the recited antibody. It is suggested that Applicants change the last parts of the claims as shown below:

--23. An ..... a portion thereof, wherein said peptide or polypeptide or a portion thereof specifically binds to monoclonal antibody 64G12 deposited at the ECACC under no. 92022605.--

--25. An ..... a portion thereof, wherein said peptide or polypeptide or a portion thereof

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specifically binds to monoclonal antibody 64G12.--

#### Remarks

- 21) Claims 24 and 26 stand rejected. Claims 23 and 26 stand objected to and would be allowable, if amended as suggested.
- 22) **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

23) Papers related to this application may be submitted to Group 1600, AU 1641 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1 (CM1). The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center's telephone number is (703) 308-4242, which is in service 24 hours a day, seven days a week.

23) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. The Examiner can normally be reached on Monday to Friday from 8.00 a.m to 4.00 p.m. A message may be left on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SD  
S. Devi  
Patent Examiner  
September 2000

  
primary ALBERT NAVARRO  
PATENT EXAMINER